

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P12829/KDG	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/SE2003/001012	International filing date (day/month/year) 16.06.2003	Priority date (day/month/year) 17.06.2002
International Patent Classification (IPC) or national classification and IPC A61K 38/17, G01N 33/68, A61P 9/10 // C07K 14/705		
Applicant Cartela AB et al		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
 - a. ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input checked="" type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application |

Date of submission of the demand 18.12.2003	Date of completion of this report 24.09.2004
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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SE2003/001012

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

- ☐ international search (under Rules 12.3 and 23.1(b))
☐ publication of the international application (under Rule 12.4)
☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

☒ the international application as originally filed/furnished

☐ the description:

pages _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

pages _____ as originally filed/furnished

pages* _____ as amended (together with any statement) under Article 19

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the drawings:

pages _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to the sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☒ the entire international application

☒ claims Nos. 1-6, 8-10, 12-15

because:

☐ the said international application, or the said claims Nos. 1-6, 8-10, 12-15 relate to the following subject matter which does not require an international preliminary examination (*specify*):

See PCT Rule 67.1.(iv).: Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods.

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____ are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐

has not been furnished

☐

does not comply with the standard

the computer readable form

☐

has not been furnished

☐

does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in the Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	<u>11, 16-18</u>	YES
	Claims	<u>7, 17</u>	NO
Inventive step (IS)	Claims	<u>11, 18</u>	YES
	Claims	<u>7, 16-17</u>	NO
Industrial applicability (IA)	Claims	<u>7, 11, 16-18</u>	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Reference is made to the following document in the International Search Report:
D1:WO9951639

D1 discloses alpha-10 integrin and suggests that this be used to analyse development of atherosclerosis. The method of claim 7 the general steps a)-c), self-evident to a person skilled in the art. In the absence of particular scores for risk subjects in comparison with control claims 7 and 17 lack novelty.

D1 which is regarded as the closest prior art differs from the subject-matter of claims 11 and 18 by not particularly emphasising that the integrin should be analysed in plaque. Even though, plaque development being the central process of atherosclerosis a person skilled in the art could in view of D1 analyse plaque for alpha-10 integrin and doing so would identify the integrin, the development of atherosclerosis involves many different types of cells or tissues and it is not certain that a person skilled in the art would analyse plaque in particular. Consequently, the invention according to 11 and 18 is be novel, industrially applicable and considered to involve an inventive step.

D1 does not mention any therapeutic role of alpha-10 integrin. However, in general, a person skilled in the art would take the presence of a molecule in a pathological condition as an indication that said molecule could be involved in that pathological condition and as a consequence a potential drug target. In the present application alpha-10 integrin has been identified in plaque, no other information how this information can be used in therapy is provided.

.../...

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: BOX V

Consequently, the application does not provide any technical information that goes beyond what a person skilled in the art would expect from the mere identification of the integrin. A person skilled in the art is left with the question how a composition comprising alpha-10 integrin could be used in treatment.

Consequently, even though the invention according to claim 16 may be novel, it has not been shown to involve an inventive step.

Moreover in view of the previous reasoning it can be questioned if the invention according to claim 16 is sufficiently disclosed in the meaning of article 5.

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

In the present application alpha-10 integrin is identified in plaque. A person skilled in the art is left with the question how a composition comprising alpha-10 integrin could be used in treatment. Therefore, claim 16 is not regarded to be sufficiently disclosed as demanded in PCT article 5.